Notice of Allowability	Application No.	Applicant(s)	
	09/403,897	BARKAN ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to _____.

2. ☒ The allowed claim(s) is/are *2-8, 28-35, 39-41, renumbered as 1-18, respectively*.

3. ☒ The drawings filed on *28 October 1999* are accepted by the Examiner.

4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____.
      3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Karen A. Canella

KAREN A. CANELLA PH.D.
PRIMARY EXAMINER

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Rodger Browdy on March 22, 2005.

The application has been amended as follows:

Claim 28 has been replaced with the following:

28. A method for treating tumors in mammals or for inhibiting tumor cell proliferation in mammals, comprising administering to a mammal in need thereof an effective amount of an active agent selected from the group consisting of:

(a) leptin;

(b) a mutein of leptin having at least 90% identity with the sequence of a leptin and has the ability to inhibit the IGF-1 induced or insulin-induced proliferation of the human breast cancer cell line T-47D or MCF7, or having a sequence encoded by a nucleic acid that hybridizes to a nucleic acid which encodes leptin under stringent conditions that include washing conditions 12-20° C below the calculated Tm of the hybrid under study, and has the ability to inhibit the IGF-1 induced or insulin-induced proliferation of the human breast cancer cell line T-47D or MCF7;

(c) a fragment of one of (a) or (b) which has the ability to inhibit the IGF-I induced or insulin-induced proliferation of the human breast cancer cell line T-47D or MCF7;

(d) a fusion protein comprising (a), (b) or (c);

(e) a salt of any one of (a)-(d); and

(f) a functional derivative of any of (a)-(d) selected from the group consisting of one or more polyethylene glycol side chains formed by means of functional groups which occur as side chains of any of (a)-(d), aliphatic esters of one or more carboxyl groups, amides of one or more carboxyl groups by reaction with ammonia or with primary or secondary amines, N-acyl derivatives of one or more free amino groups of the amino acid residues formed with acyl moieties, O-acyl derivatives of free hydroxyl groups formed with acyl moieties, and combinations thereof.

Claim 30 has been replaced with the following:

30. A method in accordance with claim 28, wherein said active agent is a mutein of leptin having at least 90% identity with the sequence of a leptin and has the ability to inhibit the IGF-I induced or insulin-induced proliferation of the human breast cancer cell line T-47D or MCF7.

Claim 40 has been replaced with the following:

40. A method for treating human breast carcinoma or for inhibiting human breast carcinoma cell proliferation, comprising administering to a patient in need thereof an effective amount of an active agent selected from the group consisting of:

(a) leptin;

(b) a mutein of leptin having at least 90% identity with the sequence of a leptin and has the ability to inhibit the IGF-1 induced or insulin-induced proliferation of the human breast cancer cell line T-47D or MCF7, or having a sequence encoded by a nucleic acid that hybridizes

to a nucleic acid which encodes leptin under stringent conditions that include washing conditions 12-20° C below the calculated Tm of the hybrid under study, and has the ability to inhibit the IGF-1 induced or insulin-induced proliferation of the human breast cancer cell line T-47D or MCF7;

(c) a fragment of one of (a) or (b) which has the ability to inhibit the IGF-I induced or insulin-induced proliferation of the human breast cancer cell line T-47D or MCF7;

(d) a fusion protein comprising (a), (b) or (c);

(e) a salt of any one of (a)-(d); and

(f) a functional derivative of any of (a)-(d) selected from the group consisting of one or more polyethylene glycol side chains formed by means of functional groups which occur as side chains of any of (a)-(d), aliphatic esters of one or more carboxyl groups, amides of one or more carboxyl groups by reaction with ammonia or with primary or secondary amines, N-acyl derivatives of one or more free amino groups of the amino acid residues formed with acyl moieties, O-acyl derivatives of free hydroxyl groups formed with acyl moieties, and combinations thereof.

Claim 41 has been replaced with the following:

41. A method in accordance with claim 40, wherein said active agent is selected from the group consisting of:

(i) leptin;

(ii) a fragment of leptin that has the ability to inhibit the IGF-I induced or insulin-induced proliferation of the human breast cancer cell line T-47D or MCF7;

(iii) a fusion protein comprising (i) or (ii);

(iv) a salt of any of (i)-(iii); and

(v) a functional derivative of any of (i)-(iii) selected from the group consisting of one or more polyethylene glycol side chains formed by means of functional groups which occur as side chains of any of (a)-(d), aliphatic esters of one or more carboxyl groups, amides of one or more carboxyl groups by reaction with ammonia or with primary or secondary amines, N-acyl derivatives of one or more free amino groups of the amino acid residues formed with acyl moieties, O-acyl derivatives of free hydroxyl groups formed with acyl moieties, and combinations thereof.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
3/31/2005

KAREN A. CANELLA PH.D
PRIMARY EXAMINER